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USERS ABILITY TO SHARE KNOWLEDGE WHEN INTEGRATED IN NEW PRODUCT DEVELOPMENT - EVIDENCE FROM THE PHARMACEUTICAL INDUSTRY

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Abstract

ABSTRACT
In technological intensive industries knowledge input from both internal and external sources is crucial (Ahuja 2000, Gulati ét al. 2000, Von Hippel 2005; Thompson 2005). A highly well informed and increasingly recognized source of knowledge is users of these technological products. By establishing and maintaining a close network with key users, firms can tap into unique knowledge, which can be useful in product development processes (Urban and von Hippel 1988, Shah 2000, Rothwell 1994). Previous studies have here pointed to the professional capabilities of users, which may generate a community of common understanding and professional frame of reference with in-house industry staff, which promote knowledge sharing (Wenger and Snyder 2000, Lynn ét. al. 1996, Franke and Shah 2002, Gulati 1998). This stream of literature acknowledge industry?s possibilities to tap into specific knowledge, there is however a gab in exploring users competences beyond their profession. Especially in down stream product development users may generate general experiences about process optimization from inclusion in the development process. This study aims at meeting this gab by exploring users ability to share knowledge about their professional experiences, but also concerning issues, which go beyond their pre-defined role. The overall research question for this paper is therefore: Can users ability to share their knowledge obtained in product development integration be differentiated by topic area? Are topic areas related to their own professional frame of reference easier transferred, than more general experiences about the

development process?
The overall research question studied further by some in-depth sub-questions related to relationship between user and producer: How is users knowledge sharing ability influenced by: (1) their job role, (2) their personal relations with the producer, (3) their possibilities to have continuous relations with the producer and lastly (4) the means of communication between user and producer.
This study thereby contributes with increased understanding of users role in down stream product development, and expand previous perspectives on utilization of highly skilled users, when integrated in development processes.
In this study we apply a unique dataset developed in collaboration with Center for the Study of Drug Development (CSDD) at TUFT University, Boston. We explore the collaboration between pharmaceutical new drug developers and the medical sites, whom are the future users of new drugs. In collaboration with TUFT CSDD a questionnaire survey were developed aiming at global network of medical sites participating in clinical trials where new drugs are tested before marked launch.
To analyze the research question the Rasch scale modeling (Rasch 1980, Bond and Fox 2001), which is part of the item response theory (IRT) (Singh 2004, de Jong ét al. 2008) is applied. The results of the Rasch model analysis reveal a variation in the difficulty of transferring knowledge by topic area. Users ability to share knowledge related directly to their medical profession is higher, than their ability to share knowledge concerning the general management of the trial process.

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USERS ABILITY TO SHARE KNOWLEDGE WHEN INTEGRATED IN NEW PRODUCT DEVELOPMENT - EVIDENCE FROM THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

In technological intensive industries knowledge input from both internal and external sources is crucial (Ahuja 2000, Gulati ét al. 2000, Von Hippel 2005; Thompson 2005). A highly well informed and increasingly recognized source of knowledge is users of these technological products. By establishing and maintaining a close network with key users, firms can tap into unique knowledge, which can be useful in product development processes (Urban and von Hippel 1988, Shah 2000, Rothwell 1994). Previous studies have here pointed to the professional capabilities of users, which may generate a community of common understanding and professional frame of reference with in-house industry staff, which promote knowledge sharing (Wenger and Snyder 2000, Lynn ét. al. 1996, Franke and Shah 2002, Gulati 1998). This stream of literature acknowledge industry's possibilities to tap into specific knowledge, there is however a gab in exploring users competences beyond their profession. Especially in down stream product development users may generate general experiences about process optimization from inclusion in the development process. This study aims at meeting this gab by exploring users ability to share knowledge about their professional experiences, but also concerning issues, which go beyond their pre-defined role. The overall research question for this paper is therefore: *Can users ability to share their knowledge obtained in product development integration be differentiated by topic area? Are topic areas related to their own professional frame of reference easier transferred, than more general experiences about the development process?*
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survey were developed aiming at global network of medical sites participating in clinical trials where new drugs are tested before marked launch.
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INTRODUCTION

In new product development processes companies are pursuing resources in their external network to optimize the knowledge and expertise necessary for the development of unique products to the market (Zaheer and Bell 2005). Users of potential new products represents a unique opportunity to utilize know-how and need-dynamics, which can stimulate in-house knowledge and learning in product development (von Hippel 1988, Shah 2000). The utilization of user insights is especially interesting in the perspective of high-tech industries, as the market often constitutes professionals with unique expertise in the product area, and therefore are an opportunity for companies to tap into cutting edge knowledge (Franke and Shah 2002; Thompson 2005).
Often such user network resources and especially resources related to knowledge exchange and input have been related to up-stream innovation processes (Powell 1996; von Hippel 1988). However, in the down-stream innovation processes external network resources may greatly benefit the firm and is therefore an important factor to consider in late stage development. There is however a need for more knowledge on the utilization of the knowledge input from this unique user network in down stream product development.
In down stream product development the new product is close to the market and issue related to market integration are therefore of great importance. Besides testing the new product concerning product specific issues, areas such as workforce required to manage the high tech product, access to the new product, the branded name and cost effectiveness are also relevant for future development for the product and market launch. With users integrated in late stage product development producers therefore not only need to be aware to utilize user resources related to their professional capabilities, but also their general experience generated from being integrated in down stream development. The presented stream of literature (von Hippel 2005, Wenger and Snyder 2000, Thompson 2005) present structures to generate and utilize the tacit knowledge (Nonaka & Takeuchi, 1995) users posses from the perspective of their professional role, but there is a gab in previous literature expanding this perspective by including knowledge generated beyond users professional profile.
This study thereby contributes with further exploration of the professional community perspective to user inclusion in down stream product development, which primarily refers back to Wenger and Snyders (2000). There is a need for further understanding of utilization of users capabilities, which go beyond predefined resources defined by profession. This is conducted by integrating scale modeling, which includes measures beyond users primary profession, and also contrasts these to traditional topic areas of interest. The model therefore both include an expanded perspective of knowledge sharing opportunities, and relate these to traditional perspective on professional users knowledge sharing capabilities.

The rasch scale is further explored by testing the effect of (1) users job role, (2) users personal relations with the producer, (3) users possibilities to have continuous relations with the producer and lastly (4) the means of communication between user and producer, on the single rasch measure generated by the scale.
To investigate users ability to share their knowledge about a new product with the producer we turn our focus to a high-technology driven industry, which are highly dependent on their users in the process of product development. We explore the relation between medical sites and the pharmaceutical industry in the process of drug development. Medical sites, as users of the new products, are highly integrated in the crucial down stream process of product development, where the new drugs are tested before being approved for market launch, and therefore a interesting case to observe utilization of user resources.

The paper proceeds as follows: (1) Conceptual framework leading to the hypothesis´. (2) Elaboration of the empirical framework under which the conceptual model is studied. Here the complex process of drug development is described more in detail focusing especially on the central stakeholders relevant for the down stream development process. (3) Description of the research methodology presenting the data and method applied in the study. (4) Results followed by discussion. (5) Reflections leading to suggestions for further research.

CONCEPTUAL FRAMEWORK AND HYPOTHESIS

Firm's capabilities are not limited to in-house resources, but external network relations are perceived as assets, which can be utilized and contribute to firm performance (Gulati 1998; Zaheer and Bell 2005). This is especially the case in the perspective of new product development processes, as it is today widely recognize that firm´ external resources can be an integral element in the development of unique products for the market. Firms cannot rely solely on their internal capabilities when developing new products, but also needs to pool external resources (Gold 1987; Zaheer and Bell 2005).
A company's external networks of stakeholders are therefore of vast importance for the processes of product development. Here pooling resources from other companies are not the only external source of input that firms utilize in product development. Von Hippel (1988) expanded the perspective on sources of innovation by presenting users as a main resource for new product developments. Users are seen as an increasing source of input in new product development, contributing to firm performance (von Hippel 2005; Shah 2000; Rothwell 1994). The perspective on users has thereby changed from actors representing market needs, which industry could try to identify and fulfill, to a perspective on users as having an actual influence on the development process and the final products ready for the market (Von Hippel 2005).

User influence in the development process is often observed in the earlier stages of development where new ideas are discovered. However, besides being an asset in up-stream innovation, users and customers are also a relevant network resource in down-stream innovation processes. Users may be integrated in the later stages of development, when new products are being tested before market launch (Shaw 1988, Thomke and von Hippel 2002; Cooper 2001). However, there is limited knowledge on the character and scope of user influences in these late stages of development, and how the knowledge from user can continuingly be integrated in the development process. Besides merely testing new prototypes, user may have a more direct role in the further development of this prototype, and the processes in the later stages of development such as the market

launch.
In high-technology markets users are in many cases professionals with unique knowledge not only about user behavior, but also about the field of the specific industry. Therefore user influence in the product development process may not only have character user-need input from user to producer, but the relation can better be characterized as a knowledge exchange among professionals, as industry staff may be from the same professional field as the users (von Hippel 2005). According to Wenger and Snyder (2000) there exist different social communities of practice where unique knowledge is defined over time and this knowledge becomes social competences within the community. Such communities are often groups of individuals with competencies within the same profession or area, which over time evolves joint understanding. These social communities together with personal competencies make it possible for new knowledge and innovation to emerge (Wenger 1998): "*In these learning systems, organizations find the talents they need, new ideas, technological developments, best practices, and learning partners*" (Wenger, 1998: 244).
Communities of practice are most often applied to define professional network relations between companies and for example universities or other knowledge centers central for high-technology product development (Lynn ét al. 1996). But in high-technology industries products are often disseminated to professionals within the field. The relations to customers and users can in many industries have the character of not only a knowledge input but also knowledge sharing through a community of practice of equal professionals with knowledge of the product area (Thompsen 2005).
The perspective of communities defined by professional frame of reference today primarily refers back to the original scholars behind the perspective (Wenger 1998, Wenger and Snyder 2000, Thompson 2005). There is limited research expanding this perspective to knowledge sharing on a broader scale and thereby including knowledge sharing ability in these communities, which is differentiated beyond topics of the professional commonality. As this relationship to professional users is a valuable source of knowledge and input into the innovation process there is a need to further explore if the users resources is optimally utilized. We therefore set out to study to which degree users ability to share knowledge is actually dependent on the knowledge being related to their professional references. As users may gain knowledge about a line of issues related to down stream product development process in general by being increasingly integrated in the process, it is relevant to integrate these topics in a study of professional communities including user and producer. We thereby aim out to study this by presenting the following overall hypothesis:

Hypothesis 1: *Users ability to share knowledge with the producer can be differentiated by topic area. Topics related to users own professional background is easier transferred to the producer, than general issues related the product and the ongoing development process.*

When studying users ability to share knowledge the role of the user and their professional qualifications is relevant, as this will qualify their knowledge sharing ability in a professional community perspective (Wenger 1998). Some users are especially emphasized and defined as 'lead users' with unique knowledge about the future end-user market of a new product, as well as specific knowledge on the product area (von Hippel 1986; Urban and von Hippel 1988; Shah 2000). These lead users may have cutting edge knowledge of the product area (Rothwell 1994) through their professional expertise and thereby represent knowledge of excellence (Shaw 1988), and form communities where they share knowledge and learn from each other (Franke and Shah 2002). We thereby

include the professional role of the users, both to validate the scale of users knowledge sharing ability developed in hypothesis 1, and to explore if the role of users is in fact influencing the process.

Hypothesis 2: *If users have a job role, which is related to the product and therefore have expertise in the area, this have a positive effect on knowledge sharing ability of the user.*

Besides having professional expertise in the product area the relationship to the producer representative are also previously mentioned as having a central role in knowledge sharing processes (Wenger 1998). Through ongoing collaboration joint understanding may be developed, which can support the flow of knowledge between partners. The scale of knowledge sharing ability should therefore also be related to the personal relationship between user and producers, which may support the flow of knowledge.

Hypothesis 3: *If users are engaged in more personal relations with the producer through ongoing collaborations, this have a positive effect on users ability to share knowledge with the producer.*

Besides being personal related through ongoing collaboration, the level of collaboration may also influence knowledge ability. User inclusion in down stream product development is traditionally observed in a more one way information flow process, where users are applied in a prototype testing process of new products, and thereby in a limited period in late stage development (Thomke and von Hippel, 2002; Cooper 2001). However, ongoing collaboration and therefore follow up discussions after testing processes can be an influential factor in the utilization of users resources (Argyris 1976).

Hypothesis 4: *If user and producer are engage in ongoing collaborations during the development process, and thereby engaged in follow up meetings, this has a positive effect on users ability to share knowledge with the producer.*

Ability to share knowledge between user and producer may also be influenced by communication mean, which can be observed both in relation to TIME, but also communication over SPACE. Communication at the same time and space supply actors with the opportunity of giving direct feed back and initial reflections to the topics discussed. Communication mean at the same time and same location have previously been explored as stimulating knowledge exchange (Gulati 1998, Porter 1998), especially through the development of social relations (Wenger 2000). However, as collaboration across distance is increasing with globalization it becomes more relevant to also explore communication, which may occur at the same time, but across distance (Baker 2002, Powell ét al. 2004, Bathelt and Turi 2011) and therefore challenges perspectives of local proximity (Porter 1998). We therefore define communication mean in three formats: 1) Same time and place, which implies a traditional face-to-face setting. 2) Same time, but not space, which can be direct communication via a virtual media such as conference calls, web conferences etc. 3) neither time nor space, which can define written communication in reports, emails etc.
When exploring users ability to share knowledge we thereby propose the following hypothesis to support the Rasch scale model:

Hypothesis 5A: *If collaborating partners have the means to communication directly with each other in time, this will have a positive effect on knowledge sharing ability.*

Hypothesis 5B: *If collaborating partners have the means to communication directly with each other both in time and space, this will have a positive effect on knowledge sharing ability.*

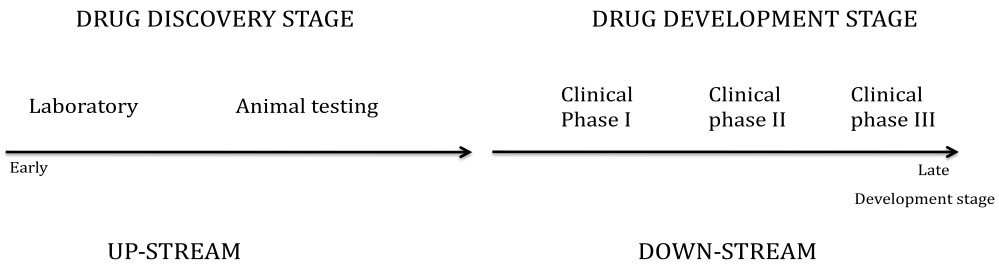
Hypothesis 5C: *If collaborating partners apply written communication means, this will have a negative effect on knowledge sharing ability.*

The overall aim of this paper is to obtain further understanding of the utilization of users knowledge when are included in the late stages of product development, where prototypes are being tested before market launch. One of the most significant prototype testing processes occurs in the Pharmaceutical industry as new products are here tested in clinical trials. Here users have a critical role, as the doctors and related staff whom late will apply the potential marketed products are integrated in the development process as these clinical personal are conducting the actual trials. By developing a scale of topic areas defining which areas are most easy to transfer in the current process – topics related to the product and therefore clinical practice aspects, or management related issues, which is in the periphery of these professional users expertise area – we can expand our knowledge of knowledge sharing dynamics with this increasingly important external resource in product development.

PHARMACEUTICAL PRODUCT DEVELOPMENT

The pharmaceutical industry is an interesting case of down-stream partnerships, as future users are directly integrated in the processes of product development. New product prospects undergo extensive testing phases following strict clinical trials, which are conducted by medical sites such as private clinics, health centers, and hospitals. The clinical trial phases have on average a duration of 8 years and cost of succeeding through all clinical phase including expenses for failed entities is estimated to an average of $ 800 million, which amount to around 50 % of the overall R&D expenses of developing a new drug (DiMasi 2001; Struck 1994; DiMasi and Grabowski 2007; European Federation of Pharmaceutical Industries and Associations Efpia - *The pharmaceutical industry in figures*. 2009 update**)**. The clinical trials are thereby a substantial element in the NPD of the industry due to the extensive time and costs spend on theses stages. This is further emphasized by the high risk of failure in the later phases, as the probability of promising new entities from the discovery phases to succeed the three clinical trial phases are only one in five (DiMasi, 2001; DiMasi and Grabowski, 2007).

FIGURE 1: *New product development process of the pharmaceutical industry*



The pharmaceutical industry is a unique example of product testing processes, as the new products undergo extensive clinical research processes, where it is required to collaborate with users as they can conduct the actual patient trials and supply the necessary information for the regulatory authorities. The physician's link to patients is a valuable asset for the pharmaceutical industry, as well as physician's expertise in the therapeutic area (Getz and Zuckerman 2010). Companies develop trial protocols as well as manuals for product use, which sites apply in the clinical trials. Feedback from the sites on safety

and efficacy of the new products are then reported back to the company and entails the application to the regulatory authorities for gaining approval of the new product to the market (Hathaway ét al. 2009). Physicians are thereby integrated in the development of new products before market launch, thus presenting an example of how users in some industries are a central player in the down-stream processes.

The relationship between the in-house clinical staff and the clinical investigators at hospitals has similarities to Wenger (1998) communities of practice. In drug development professional communities of individuals are developed over time, which generate optimal opportunities of knowledge sharing. *Direct clinical participation represents a way for sponsor companies to develop strong relationships with practicing physicians, not only by communicating with potential prescribers, but by learning directly from them as well* (Glass 2004 in Pharmaceutical Executive). As the study from Glass (2004) illustrate, the down-stream network with physicians have an impact on the development process, as industry clinical staff and physicians at medical sites interact and exchange knowledge. This is also mentioned by Danzon ét al. (2005) in relation to trial experience and the impact of relations to physicians for trial success. *Learning-by-doing may produce general and category-specific skills in designing and managing trials, and improve relationships with clinicians and regulators, thereby contributing to trial success rates* (Danzon ét al. 2005, 319). This corresponds with the perspectives mentioned by Wenger (2000) as the communities of practice generating knowledge exchanged are generated over time. The continuous relationship between companies and the physicians developed over time thereby creates conditions, which may generate what von Hippel (1988) identified as informal knowledge exchange, and be a unique source of input to the late stages of development in the pharmaceutical industry.

The positive relation between trial success and experience found by Danzon ét al. (2005) point to trial processes such as designing and managing trials, and continuous relationships to clinical sites and therefore physicians. This study is interesting, as it illustrate that the process of user integration in the testing process not only is a matter of standardized feedback, but that the actual relationship between users and industry in the down-stream development process are important, and that the network created over time may influence trial outcome. Another example of the influence of users in the trial phases has in previous studies been illustrated in relation to market introduction. Glass (2004) has studied the influence of the relationship to physicians in relation to the adoption of the new products to the market. These studies point to the importance of physician-industry relations, as physicians participating in clinical trials are more likely to prescribe the new product after market launch. Sismondo (2008) discuss this phenomenon and mentions how clinical trials familiarize physicians with the new products, which may impact their behavior in relation to prescribing the new product and therefore influence the performance of the new product on the market.
Extant literature has thereby emphasized the importance of these central users in drug development. There is however little industry specific knowledge about the utilization of the knowledge gained by medical site representatives through this extensive participation in down stream product development processes. The formalized relation is based on extensive reporting concerning clinical aspects of the testing process, however focus on information gained beyond these formalized processes is not explored. This study therefore both contribute with knowledge about the current processes and how this promotes user ability to share knowledge concerning traditional topics of clinical relevance to the drug, but also additional topic areas, which is not the primary focus of the collaboration.

RESEARCH METHODOLOGY

Data

To test the hypothesis´ we carried out a study among medical sites participating in clinical trials in pharmaceutical drug development processes. These site representatives are difficult to locate and identify, however TUFT center for the Study of Drug Development have a unique dataset of clinical sites amounting to over 1500 respondents. This unique dataset was therefore applied and from this a questionnaire developed. 395 site representatives responded the questionnaire, which therefore supply a substantial sample size, especially as this population of clinical investigative site representative is hard to engage in contact with.

In developing a questionnaire matching the aim of the study, both expertise of the drug development research group at TUFT CSDD, and the innovation management group from TU Berlin and DTU was applied as to both include elements specific to NPD and specific drug development terminology.

The content of the questionnaire focused on users participation in product testing processes and here on users ability to share their knowledge, and issues that may affect this process of knowledge transfer between user and producer in product development collaborations.

Table 1: *Description of the variables applied in this paper*

Variable	Specifications	Applied as
Ability to share knowledge	Site representatives ability to share knowledge is studied by specifying 11 topic items. These are all measured on a 4 point Likert scale. The 11 items are applied in a Rasch scale model. Besides the Rasch analysis a single Rasch score measure is also computed, which is applied as the dependent variable in a regression analysis.	Rasch scale items Combined in Rasch measure and thereafter as dependent variable in regression analysis
Job role of site representative	Grouped in to two overall roles: 1) Clinical investigators. 2) Supporting staff	Explanatory variable in regression analysis
Personal relations between site and producer	4 point Likert scale, integrated as dichotomous variable in the regression model	Explanatory variable in regression analysis
Post trial follow-ups	3 point Likert scale, integrated as dichotomous variable in the regression model	Explanatory variable in regression analysis
Communication mean	Specified in three communication variables: Direct communication face-to-face, Direct communication across space, Written communication.	Three explanatory variables in regression analysis

In order to obtain a rich measure for *users ability to share knowledge with the producer*, the question were divided in to 11 sub questions covering 11 topic areas. The items were developed by studying the clinical practice guidelines, which is the document medical sites apply in the use of a specific medical drug. These clinical practice guidelines supply information about the topics and also wordings applied by both the users and the specialized personal at the producer site of the process. From studying the kind of topics relevant for drug development, and also studying the pharmaceutical product development process in general 11 topic items were formulated. These 11 topic items can be defined in to two areas of knowledge related to the product development process: 1) clinical issues directly related to the effectiveness of the new product. 2) Management related issue connected to the product and the ongoing development process. The division between the two groupings is general and some issues can be considered as overlapping. They are however assigned to the grouping where their main function is applied.

Table 2: *Overview of the 11 item topics, which the respondents from medical sites had to answer about their ability share knowledge.*

Item No.	Question content	Issue item
1	Drug side effects	Clinical practice
2	Administration of the new drug (e.g. taken with meal, taken in the evening, on empty stomach etc.)	Clinical practice
3	Concomitant drug interactions	Clinical practice
4	Delivery form (tablet, capsule, injection etc.)	Clinical practice
5	Dosage of new drug	Clinical practice
6	Cost effectiveness of new drug	Product management
7	Patient access to the drug	Product management
8	Risk/benefit from intervention	Clinical practice
9	Clinical skills necessary for successful drug administration	Product management
10	Workforce required for drug administration	Product management
11	Patients and professionals reaction to branded name	Product management

Rasch scale modeling

To study how users ability to share knowledge with the producer may be differentiated by topic area, the rasch scale modeling is applied, (Rasch 1980, Bond and Fox 2001) which is part of the item response theory (Singh 2004, de Jong ét al. 2008). Instead of focusing on dependent and independent variables, item response theory focus on measuring related items and how they may be positioned and then observed on a scale (Singh 2004). A rasch scale model is thereby applied to evaluate the relationship between the items, which is measured by probability statistics modeling (Singh 2004; Rasch 1980).

The Rasch model define an order of the items by assigning difficulty based on the 4 point likert scale applied for each respondent. The rasch scale therefore observes the

relationship between items and persons. In our analysis we are however primarily interested in the relationship between the items, but the scale of persons are related and contribute with indications of model fit (Bond and Fox 2001). If the item-person map does not correspond it implies, that the chosen items does not describe the issue area in question, which in this case is person's ability to share knowledge. Item fit statistics will thereby supply information concerning the fit between the rasch scale model and the observed data. Such infit/outfit measures can be identified in the analysis and will be elaborated on in the result section.

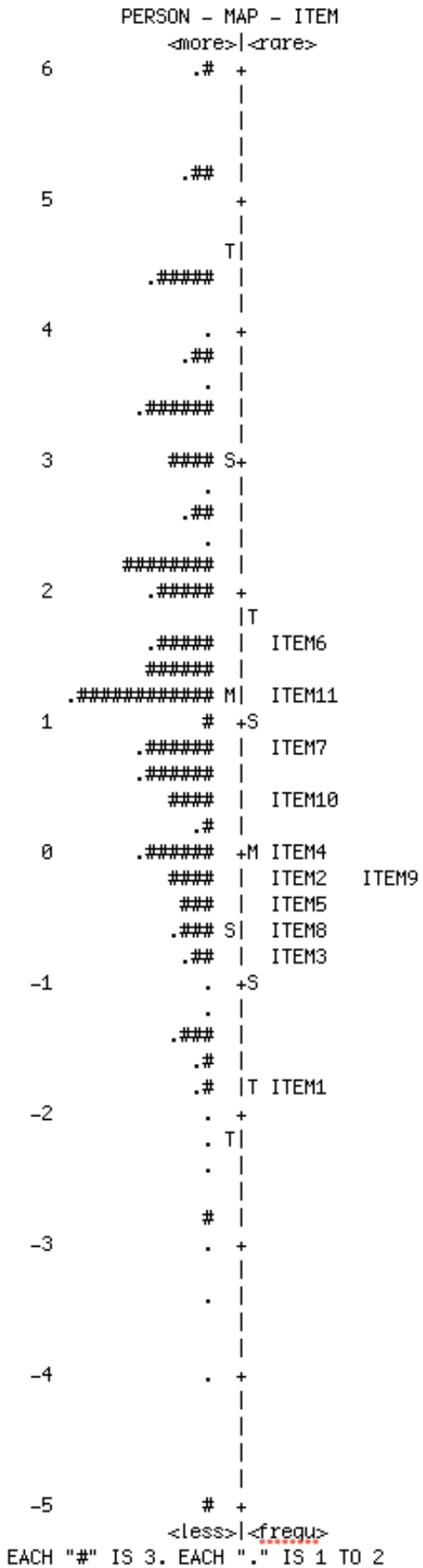
The scale will not only give a relative order of the items, but also scale the items as more or less difficult on a common continuum. The measure can therefore support an analysis of users ability to share knowledge about the identified item issues, which is divided in two overall areas, both relative to each other to identify a pattern, and hereafter to order the difficulty of items.

Besides presenting a scale, which make it possible to related topics items directly to each other, the scale also produce a single measure representing the scale. The Rasch measure can be defined as the likelihood of a certain item topic to score high in the likert scale answered by the respondents (Bond and Fox 2001). The measure therefore integrates a loading of the item topics in an overall measure and represents a differentiated measure, than if a mean of all item areas was developed.
In order to validate the scale this measure is further explored in a regression analysis, where the relationship between the Rasch measure of sites ability to share knowledge with the producer and related variables are further explored. Besides strengthening the validity of the Rasch measure, the regression model is also applied to explore the Rasch measure analysis further.

RESULTS AND DISCUSSION

To address hypothesis 1 a scale-modeling tool is applied in order to identify if knowledge sharing ability can be differentiated according to topic area. The 11 topic items, which is categorized in clinical practice issues and product management issues, are therefore entered into a rasch scale model, which illustrate tendencies in the respondents answers concerning the items. All issues were addresses as a 4 type Likert-scale, which was included as the item measurement, and the individual respondent IDs as person measurements. Figure 1 illustrates the rasch map generated by the Rasch scale modeling program Winstep (Linacre 2010). Left side show the respondents and how they respond on the scale isolated and in relation to items. On the right side of the continuum the items are outlined in relation to each other.

Figure 2: *Item-person map – Winstep output*



Fit statistics are computed in the rasch analysis and supply information concerning the fit of the data in relation to the rasch output map. The mean square values should have an expected value around 1, but values will exist above and below this with max. limits defined as ceiling effects, and minimum values as floor effect. If the MNSQ *infit* values are significantly lower than 1 some dependencies are present in the data, and if higher than 1 then some noise should be considered in the model (Linacre 2010). Further, MNSQ *outfit* level significantly lower than 1 also imply dependency in the data, while an MNSQ *outfit* level significantly above 1 indicate that there is some unexpected outliers in the chosen variables.

Table 3: *Fit statistics, Rasch analysis*

Item	Difficulty	MNSQ	
		Infit	Outfit
1	-1.89	1.29	1.32
11	1.26	1.19	1.22
6	1.57	1.14	1.15
4	.07	1.03	1.09
5	-.44	.98	.96
2	-.18	.91	.96
8	-.59	.93	.87
3	-.74	.90	.90
7	.80	.90	.87
9	-.27	.81	.78
10	.41	.77	.75

Difficulty: degree of users ability to share with producer reflected in the specific item.

A rule of thumb is a level within +/- .2 (.80/1.2) (Bond and Fox 2001). Item number 1 therefore shows some sign of both noise and outliers, and item 8 show tendency to dependency in the data. The MNSQ fit statistics for item 1 and 8 is however not substantially different than 1, and is both critical issue within the empirical area studied – clinical trials, and is therefore kept in the model. This should however be considered if special conclusions about item number 1 isolated is made. As mentioned in the introduction we primarily observe the items as part of a grouping – clinical practice issue or product management issues – and as so the items with borderline fit statistics are kept in the model.

In item statistics the measurement method of the individual items can support reliability of the model, if the measurement items are alike. However, this can create some validity issues, which is better supported if the item measurements are different from each other (Singh 1984). In this study´ rasch analysis the item measurements are alike and therefore the model reliable. However, the tradeoff can be an under-identifying power of the model, as some issues may not be covered by the scale. This can be observed in the model by the person measurements in the left side of the model. There is an over-representations of person items in the top of the model in relation to the items. The model may therefore represent a reliable relation between the 11 items in question, but also suggest, that more issues may be considered concerning knowledge issues in clinical trials in future studies.

Besides item 1 and item 10, which reflect some fit challenges to the model, the rest of the items are well represented within the fit limits in rasch analysis. This therefore indicates,

that the managerial issues as well as the clinical issues poses knowledge sharing ability, and therefore represents user resources. The model therefore illustrate that managerial issues are relevant to pursue in utilizing user capabilities. The model however also illustrate that the managerial issues are more difficult to transfer, which both can be due to the profile of the users, and the existing processes of perceiving and utilizing users resources.

The Rasch analysis illustrates a difference the difficulty of user ability to share their knowledge with the producer. Overall there is a tendency for clinical issues to be easier to share than more management related issues. The topics defined as managerial issues (Item 6,7,9,10,11) are all in the half part of the scale, which represents the most difficult topics to share knowledge about. Topic 9 however, shows a slightly different pattern than item 6,7, 10 and 11. These 4 items are all clearly represented as the 4 most difficult items, whereas item 9 is in the middle of the scale with items related to clinical practice. When we look further at item 9 we can also see, that the topic may be borderline clinical practice, as it questions the clinical skills necessary to administrate the new drug. It thereby relates to a managerial issue in relation to workforce, however also directly to clinical practice as it concerns the clinical staff resources.
Further, on the other end of the scale we find item 1, 3. 8 and 5 as the easiest to transfer. This also correlates well with clinical practice, as theses issues – drug side effects, and drug interactions, risk/benefit from intervention and dosage of new drug – are some of the key issues in clinical trials.
The rasch scale outcome therefore shows a pattern, which relates well to the categorization of topics in clinical issues and managerial issues. This also corresponds with the conceptual framework presented in this paper. The relationship between users and producers are traditionally build on close relationships between in house partners in industry and clinical investigators, whom have their professional frame of reference in common. Hypothesis 1 questioning users ability to share knowledge with the producer to be dependent on topic area, as topics related to patterns professional frame of reference is easier transferred, is thereby confirmed.

To further test the rasch model individually, and to test the related hypothesis as formulated in H2-H5 a regression analysis is conducted. The rasch analysis generates a single rasch score, which is applied as the dependent variable. We therefore now turn to the regression analysis, which can both validate the rasch measure generated in the rasch analysis above, and test the effects proposed in hypothesis H2-H5.

Influence of user job roles on users knowledge sharing ability
The job role of the respondents is included in the questionnaire as the overall research framework indicates, that the professional background of the site representative is important to the ability to share knowledge. In line with studies such as Wenger 2000, Shaw 1988 and Lynn ét al. 1996 we propose, that respondents with a relevant professional background and in this empirical case therefore an investigative role will have a positive effect on users ability to share knowledge. Further, this can also validate if the scale, which expands previous research by integrating managerial issues in the model.
The variable is divided in to groupings: 1) Investigators and sub-investigators. These are the responsible physicians connected to a trial, and therefore also someone with a medical background relevant to the product area. 2) Supporting staff. These included administrative staff and nurses, whom are both connected to the trial. The regression model reveal a highly significant positive effect of job role on users ability to share their

gained knowledge with the producer (Unst. coef. B: .66, *t:* 2.93). The analysis thereby shows that the scale of knowledge sharing ability with managerial issues being most difficult to transfer relates to the job role of the respondents. As such there is a difference in the ability to share knowledge whether the site representative has a clinical role or a supporting role. The significant effect of job role indicates that all of the items relates to both job roles, and therefore that both roles have the opportunity to share knowledge, but the ability differentiated by topic area are different.

Influence of personal relations on users knowledge sharing ability
Previous research reveals a positive influence of experience on previous relations to sites on trial success. This study therefore tests the effect of users personal relationship with producer representatives had an influence on their ability to share their knowledge gained during the trial process. The regression analysis revealed a significant positive effect of personal relations on users ability to share knowledge with the producer (Unst. coef. B: .79 , *t:* 2.08). We can thereby confirm H2 as personal relations have a positive effect on knowledge sharing ability. This support the arguments put forward by previous scholars stating that continuous relations may create social embeddedness among actors (Gulati 1998), and further communities often defined by professional characteristics (Wenger 2000).

Influence of post testing efforts on users knowledge sharing ability
Another issue of potential influence to knowledge sharing ability questions some classical models of user inclusion in late stage product development. In these down stream processes users are often included only as a source of information about prototype testing, which is limited to a specific time in the development process (Cooper 2001, Schmidt 2005). However, ongoing learning loops (Argyris 1976) may both support the above issue of generating continuous relations, but also create some post testing opportunities for users to share additional knowledge aside from the official reporting concerning a trial. We therefore studied users experience with post trial meetings in relation to clinical trials, and asked if medical sites experienced post trial meetings with the producer after the trial is over. The effect of these post trial initiatives turned out significant (at $p < 0.1$) with an unstand. coefficient of .47, and a t value 1.68. The study thereby supports hypothesis 3 proposing that post-trial efforts have a positive effect on users ability to share knowledge. This supports a more inclusive perspective on user inclusion in down stream development, and therefore expanding traditional perspectives of users role in late stage product development. By establishing both personal and ongoing relations with users producers can gain more knowledge from this unique source of information.

Influence of communications means on users knowledge sharing ability
The research framework applied in this study indicates, that an integration of the diverse partners in a social setting often defined by similar professional frame of reference may promote knowledge sharing. Related to this perspective is the issue of communication mean, as it is implied in the mentioned studies, that such a relation is often created via face to face interactions on occasions such as conferences of direct meetings (Wenger 2000), which relates to theories on local proximity (Porter 1998, Gulati 1998). Studies on communication means on knowledge sharing have however expanded this perspective, by integrating a global dimension to this issue (Baker 2002, Powell ét al. 2004, Bathelt and Turi 2011). As global activities increase, so does also the communication across large distances. This have brought by many technological opportunities in which partners

can communicate directly with each other even though not in the same locations, such as tele- and web conferences (Baker 2002, Bathelt and Turi 2011). This issue can be defined as a differentiation among TIME and SPACE, as partners may communicate at the same time, but across geographical space. We follow this division of communication mean in this study, as clinical trials have experienced a great globalization in the last years, and therefore often have multiple sites on many global locations integrated in one trial. We therefore make three variables in relation to communication mean in order to test this issue further: 1) Direct communication, face-to-face. Includes communication between site and producer on the same location and therefore both same time and space. This could be on site meetings or off site conferences. 2) Direct communication, across space. Include communication between site and producer at the same time, but on different locations. This could be telephone conferences or web based meetings. 3) Written communication. Includes communication between user and producer, which is not bound to same location or same time. This could be emails or other written communication.
The regression analysis reveals that written communication does not have a significant effect on users ability to share knowledge. However, both face-to-face communication (Unst. coef. B: .49, *t:* 1.9) and communication across space (Unst. coef. B: .97, *t:* 3.52) have a positive effect. Besides the effect both variables have on knowledge sharing ability and therefore support the rasch scale analysis, it is also interesting to observe, that especially communication across space have a high *t* value, which therefore supports studies of knowledge sharing across distance. This expands previous research claiming that proximity promotes these social relations among professional, which generate knowledge sharing. Global connections are possible in today's collaborative connections in new product development.

Table 4: *Regression results: Effect of the explanatory variables on users ability to share knowledge with the producer (Defined as the Rasch measure).*

Explanatory variables	**Unstandardized Coefficient**	***t* value**
Personal relations	.79**	2.08
Post trial efforts	.47*	1.68
Job role	.66***	2.93
Communication means		
- Direct communication, face to face	.49*	1.90
- Direct communication, across space	.97***	3.52
- Written communication	-.03 n.s.	-.08

**=p < 0.1, **=p < 0.05, ***=p < 0.01, n.s = not significant*

The pharmaceutical industry is an example of an industry that has entered into a more network-oriented strategy in product development. However, it is also an example of an industry that may not fully be exploring the possibilities that exists in the unique relationship to down-stream external stakeholders of the NPD process.
Late stage network partners are primarily perceived as providers of a necessary service in the testing of new products, who can supply concrete and pre-defined information of the

clinical trials. However, these network partners, the medical centers, are highly qualified knowledge workers whom get in-depth knowledge about the product and the related managerial challenges by their long lasting integration in the down stream process. The users have a very transparent and clear role in down stream development, but this clear role may prevent the producer from tapping knowledge which go beyond the issues and tasks medical users are integrated to perform. Users gain general knowledge about the development process, which could be relevant, both in the further development of the product, and especially in the market launch and integration. This study therefore suggest that when users are integrated in a process due to their professional capabilities, experiences that go beyond this is relevant to tap into and utilize in the further development of the product.

CONCLUSION

Previous research have pointed to the importance of user-producer relations, which rely on the professional frame of reference created over years of relations, but representing a gab concerning issue areas beyond users professional competences. Meeting this gab this study firstly explored users ability to share knowledge by topic area, and therefore differentiating knowledge sharing in areas where users have their main capabilities, and then issues related more to the management of the production process. The analysis showed a difference as issues related to users main competences are easier transferred, than management issues. Second, this study explored which factors have an influence on users knowledge sharing ability, when differentiating by topic area. This was explored by testing the effect of users job role, their personal relations with the producer and the continuing relationship. All these issues had a positive effect on users ability to share knowledge, and therefore confirmed that the professional community of knowledge over time matters in knowledge sharing between user and producer in high tech production processes. It was also tested if communication mean had an effect on knowledge sharing ability, and here the analysis showed a positive effect of both direct communication face-to-face, but an even stronger effect of direct communication at the same time, but not at the same location, which expand extant proximity studies.

This study thereby expand on previous research on professional users role in new product development, by focusing on down stream product development where users may gain knowledge which go beyond their expected competences, just by participating in the process. However, their ability to share this knowledge is more difficult, than knowledge connected to their profession, which thereby represents a challenge in the utilization of user capabilities in their expanding role in down stream product development.

REFLECTIONS ON FURTHER RESEARCH

The expenses of clinical trials are continuingly increasing in the pharmaceutical industry even though more products are not entering the market (Kaitin 2010). There is therefore a common understanding in the industry that the extensive time-consuming and costly development process needs to be more effective. These motives have made pharmaceutical companies outsource previous in-house competences, such as site selection and data management, which are both closely connected to the relationship to trials, to a broker agent ((Howells 2006; Hargadon and Sutton 1997; Bessant and Rush 1995; Gould and Fernandez 1998) which is referred to as a contract research organization (CRO) in the drug industry (Getz and Zuckerman 2008). The use of outsourcing to a

broker agent in the late stage of drug development now often included CROs managing the direct relations to trial sites as companies outsource clinical trial processes in a full service partnership (FSP) (Getz and Zuckerman 2008; Bodenheimer 2000). The CRO thereby mediates the relationship between two key actors in drug development and it is therefore relevant to take on a brokerage perspective. Tasks of product development are not only outsourced to a second party, but the CROs are increasingly becoming a third party agent between network relations in the clinical trials.

It has been recognized that the integration of a CRO may generate savings on cost and time (Getz 2007; Kaitin 2010) as these organizations are specialized in the down-stream task of clinical trial management. There is however limited research focusing on the challenges the integration of a third part agent may course to the utilization of the users capabilities in down stream product development. The direct tie between sponsors and clinical sites may be jeopardized as the task of trial management are not perceived as a core competence and therefore moved to a third party agent. When the relation to the medical sites are being moved to a third party agent the utilization of knowledge from the highly competent user at medical sites may be compromised. *The use of CROs to run clinical studies can make it more challenging for pharma companies to develop relationships with investigators* (Glass 2004 in Pharmaceutical Executive).

CROs often have multiple contracts in the industry simultaneously and are naturally not as integrated in the knowledge about new products build over many years of research and development as the in-house clinical staff. The flow of unique knowledge obtained in the clinical trial phases may therefore be compromised in the new structures of drug development, which should be further explored in future studies.

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